



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: D'Angio et al.

Confirmation No.: 7850

Application No.: 10/608,077

Group Art Unit: 1614

Filed: June 30, 2003

Examiner: Roberts, L.

For: PHARMACEUTICAL
COMPOSITIONS AND DOSAGE
FORMS OF THALIDOMIDE

Attorney Docket No.: 9516-034-999
(JD 501872-999033)

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to Applicants' duty of disclosure under 37 C.F.R. § 1.56, and further to the personal examiner interview held on December 15, 2005, Applicants submit the following statements and references for the Examiner's review and entry into the record of this application.

As discussed during the interview, the following thalidomide formulations, or the mere names thereof, are known to Applicants:

- Contergan[®] from Chemie Grunenthal, Germany
- Talizer[®] from Serral S.A. de CV, Mexico
- Sauramide[®] from Penn Pharmaceutical Services, U.K.
- Thalidomide Laphal from Laphal, France
- Thalidomide Laphal sold by Pharmion, U.K.
- Thalix[®] from Dabur Pharma Ltd., India
- Myrin[®] from Lipomed AG, Switzerland
- Formulation by Tortuga, Brazil
- Formulation by EntreMed, Inc., U.S.A.
- Formulation by Microbiologica Quimica, Brazil
- Distaval[®], Softenon[®], Sedalis[®], Talimol[®], Pantosev[®], Neurosedyn[®], and Kevadon[®], the sources of all of which are unknown

Documents known to Applicants that mention the formulation names, refer to the formulations or to the existence thereof, are listed on the enclosed form entitled "List of References Cited by Applicant." Many of these formulations are already of record through certain art cited by the Examiner. This statement is not any admission that any such

formulations are prior art under 35 U.S.C. §§ 102 and 103, but the information is submitted herewith in an abundance of caution.

In addition, certain other references are also listed in the form for the Examiner's review. Copies of the references are also provided herewith.

Finally, identification of the foregoing information or references is not to be construed as an admission of Applicants or Attorneys for Applicants that such formulations, publications or information are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review this submission and the references cited therein and make them of record by completing and returning the enclosed List of References.

A fee of \$180.00 is believed to be due for the submission of this statement since it is being submitted after a first Office Action on the merits in the above case. Please charge this and any other fees to Jones Day Deposit Account No. 50-3013.

Date January 6, 2006

Respectfully submitted,



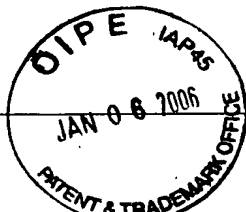
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Enclosure



LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

9516-034-999

APPLICATION NO.

10/608,077

APPLICANT

D'Angio et al.

FILING DATE

January 14, 2003

GROUP

1614

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C08	"Thalidomide," Printout from www.grunenthal.com/cw/en_EN/html/cw_en_en_aboutus.jhtml?CatId=cw_en_en_aboutus_e_01 (date unknown)
C09	"Getting Thalidomide," Printout from http://www.4imago.com/mpd/mexico.htm (May 12, 2004)
C10	"Talizer," Printout from http://216.239.37.104/translate_c?hl=en&sl=es&u=http://www.facmed.unam.mx/bmnd/pl (date unknown)
C11	"Sauramide," Printout from http://www.kodc.or.kr/jaga/suaramide_photo.htm (date unknown)
C12	"Notice Destinee Au Patient," Notice to Patients regarding Thalidomide Laphal (date unknown)
C13	"Historical Timeline," Printout from http://www.pharmion.com/corporateweb/home.nsf/Content/HistoricalTimeline (date unknown)
C14	"Thalidomide 100 mg Tablets (EntreMed Formulation)," Celgene internal document (date unknown)
C15	"Products," Printout from http://www.daburpharma.com/htmls/prod_form.html (date unknown)
C16	"Myrin (Thalidomide)," Printout from http://www.lipomed.com/Pharma/myrin/overview/ (date unknown)
C17	"Thalidomide," The Merck Index, 11 th Ed., p 9182 (1989)
C18	"Thalidomide," The Merck Index, 12 th Ed., p 9389 (1996)
C19	"Thalidomide," The Merck Index, 13 th Ed., p 9323 (2001)
C20	Guo <i>et al.</i> , "A prototype intelligent hybrid system for hard gelatin capsule formulation development," <i>Pharmaceutical Technology</i> , p.p. 44-60 (September, 2002)
C21	Rouhi, "Thalidomide," <i>Chemical & Engineering News</i> , p.p. 122-123 (June 20, 2005)
C22	"Thalidomide," <i>Drugs of the Future</i> , Entry # 91361 (2005)
C23	Abdel-Razeq <i>et al.</i> , <i>Drugs of the Future</i> , 29(10): 1059-1063 (2004)
C24	Sommer, <i>Drugs of the Future</i> , 24(1): 67-75 (1999)
C25	"Thalidomide," <i>Drug Data Report</i> , 17(5): 468 (1995)
C26	"Thalidomide," <i>Drug Data Report</i> , 17(5): 482 (1995)
C27	"Thalidomide," <i>Drug Data Report</i> , 20(11): 962 (1998)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.